

ABSTRACT OF THE DISCLOSURE

The present invention provides an *in vitro* method of diagnosing the presence of a pre-malignant lesion, a malignancy, or other pathologic condition, in a subject, which is characterized by the presence of activated matriptase including the steps of: (A) obtaining a biological sample from a subject that is to be tested for a pre-malignant lesion, a malignancy, or other pathologic condition; B) exposing the biological sample to a detectable agent which recognizes and binds to activated matriptase; and (D) determining whether said detectable agent is bound to the biological sample. Preferably, the detectable agent is an antibody which specifically binds to activated matriptase. More preferably the antibody is selected from M69 and M123. The invention also provides a method of treating malignancies, pre-malignant conditions, and pathologic conditions in a subject which are characterized by the activated form of matriptase including administering a therapeutically effective amount of an agent capable of blocking the activity of active matriptase.